APR - 9 2002

K010281

Merox Bipolar Pacing Lead
510(k) Notification

1. 510(K) SUMMARY

Name and Address of Sponsor:		BIOTRONIK, Inc. 6024 Jean Road Lake Oswego, OR 97035
Establishment Registration Number:		1028232
Device Name:	Proprietary Name:	Merox Leads
	Classification:	Class III (21 CFR 870.3680(b))
	Classification Name:	Cardiovascular Permanent Pacemaker Electrode
	Product Code:	DTB
Date Prepared:		April 4, 2002

General Description:
The BIOTRONIK Merox lead is a bipolar, passive-fixation, endocardial pacing lead with a segmented tip, available in straight and "J"-shaped conformations, for placement in the ventricle or atrium. The designation MEX xx/15-BP refers to Merox straight leads, which are available in lengths (xx) of 53 or 60 cm; MEX xx-JBP refers to Merox "J"-shaped leads, which are available in lengths of 45 and 53 cm.

The MEX xx-JBP model has a permanent bend proximal to both lead electrodes, resulting in the distal portion of the lead body having what is commonly referred to as a "U" or "J" shape. This lead shape facilitates placement in the right atrial appendage.

Merox MEX xx/15-BP and MEX xx-JBP leads are silicone insulated, featuring four silicone tines for passive-fixation in the heart's trabeculae. The tip electrode is made of a platinum/iridium base material, with a fractal iridium surface and an electrically active surface area of 1.3 mm^2. The fractal-coated, electrically active surface area is arranged in four segments on a larger geometric surface. This configuration is designed to form a beneficial relationship between tissue contact and stability by reducing the occurrence of local intracardiac tissue inflammation and microdislodgment. The ring electrode is made of a platinum/iridium base material, with a fractal iridium surface area of 22.6 mm^2. The lead conductor consists of quadrifilar MP35N wire in a coaxial configuration, insulated with silicone rubber tubing. All Merox leads utilize a 3.2 mm IS-1 connector.

BIOTRONIK proposes the following leads cleared through 510(k) notifications as predicate devices for the Merox lead:

- BIOTRONIK's Synox bipolar, passive-fixation, straight and J-shaped endocardial leads (K991169, cleared 07/01/99 and #K980869, cleared 09/10/98, respectively).
- BIOTRONIK's Polyrox bipolar, passive-fixation, endocardial lead (#K000763, cleared 04/06/00).
- BIOTRONIK's TIJ unipolar, passive-fixation, endocardial lead (#K953044, cleared 09/27/96).

Indication for Use:
Merox passive-fixation, endocardial, pacing leads (MEX 53/15-BP, MEX 60/15-BP, MEX 45-JBP, MEX 53-JBP) are intended to provide permanent pacing and sensing in the atrium and or ventricle when used with a compatible pulse generator.

Clinical Data Summary:
A clinical study is being conducted outside of the U.S. to support the substantial equivalence of the Merox lead to the Synox lead. The study started with the first implant on January 17, 2001. As of September 13, 2001, there have been 108 Merox pacing leads implanted (35 atrial, 73 ventricular). The following summarizes the study findings to date:

- The rate of possible Merox lead-related complications is 0.063 per patient-month (8 complications in 127 months).
- The mean ventricular pacing threshold is 1.1 ± 0.8 V.
- The mean atrial pacing threshold is 1.3 ± 0.9 V.
- There have been two patient deaths reported, both of which were unrelated to the pacing system.
- There have been no unanticipated adverse events reported.

Name and Address of Manufacturing Site:
BIOTRONIK GmbH & Co. (reg. no. 9610139)
Woermannkehre 1, 12359 Berlin, Germany
011-49-30-689-05-304

Contact Person(s) and Phone Number:
Jon Brumbaugh
Director, Regulatory Affairs
Phone (888) 345-0374 Fax (503) 635-9936

Name and Address of Contract Manufacturing Site:
BIOTRONIK AG (reg. no. 8043892)
Ackerstrasse 6
8180 Bülach, Switzerland
011-41-1-864-5169

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2002

Mr. Jon Brumbaugh
Director of Regulatory Affairs
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Re: K010281
Trade Name: Merox Passive-Fixation Endocardial Pacing Lead
Regulation Number: 21 CFR 870.3680
Regulation Name: Permanent Pacemaker Electrode
Regulatory Class: Class III (three)
Product Code: DTB
Dated: January 16, 2002
Received: January 17, 2002

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

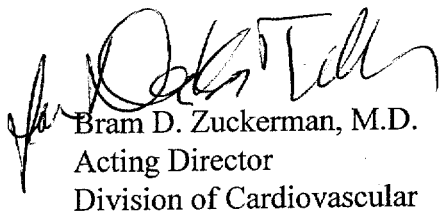
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010281

Device Name: Merox Passive-Fixation Endocardial Pacing Lead

Indications For Use:

Merox passive-fixation, endocardial, pacing leads (MEX 53/15-BP, MEX 60/15-BP, MEX 45-JBP, MEX 53-JBP) are intended to provide permanent pacing and sensing in the atrium and or ventricle when used with a compatible pulse generator.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010281

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)